# EXHIBIT - B

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### IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF TEXAS MARSHALL DIVISION

1. THE ROCKEFELLER UNIVER	RSITY§	
and	§	
2. CHIRON CORPORATION,	§	
	§	
Plaintiffs,	§	
	§	CIVIL ACTION NO. 2-04CV-168-TJW
<b>v.</b>	§	
	§	
1. CENTOCOR, INC.	§	
and	§	
2. ABBOTT LABORATORIES,	§	
	. §	
Defendants.	§	

### STIPULATED PROTECTIVE ORDER

WHEREAS, The Rockefeller University, Chiron Corporation, Centocor, Inc. and Abbott Laboratories, the parties to this action (collectively the "parties" and individually a "party"), and likely third party witnesses possess confidential information which may be disclosed in responding to discovery requests or otherwise in this action and which must be protected in order to preserve the legitimate business and other interests of the parties, and

WHEREAS, the parties have, through counsel, stipulated to the entry of this Protective Order to prevent unnecessary dissemination or disclosure of such confidential information,

#### IT IS HEREBY ORDERED that:

### 1. <u>Definitions</u>

a. The term "Confidential Information" as used in this Order is to include all information that the designating party believes constitutes or discloses or relates to processes, operations, research, technical or developmental information, production, marketing, sales, shipments or other proprietary data or information of commercial value, including but not

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limited to trade secrets. It may include, without limitation, documents produced in this action, during formal discovery or otherwise; documents and information produced by third parties which the producing or designating party is under an obligation to maintain in confidence; answers to interrogatories and responses to requests for admission or other discovery requests; deposition transcripts; and tangible things or objects that are designated confidential pursuant to this Order. The information contained therein and all copies, abstracts, excerpts, analyses or other writings that contain, reflect, reveal, suggest or otherwise disclose such Confidential Information shall also be deemed Confidential Information. Information originally designated as Confidential Information pursuant to this agreement shall not retain Confidential status after any ruling by any Court denying such status.

- b. The term "designating party" means the party producing or designating documents or information as Confidential Information under this Order.
- The term "receiving party" shall mean any person to whom c. Confidential Information is disclosed.

#### **Designation of Confidential Information**

- 2. Any party who produces or discloses any material that it believes comprises Confidential Information shall designate the same by marking "CONFIDENTIAL" on all documents containing the information.
- 3. If a producing party elects to produce original files and records for inspection and the inspecting party desires to inspect those files, no confidentiality designations need be made by the producing party in advance of the initial inspection, but the party inspecting such files and records shall maintain the confidentiality of all those original files and records that it reviews. Thereafter, upon selection of specified documents for copying by the inspecting party, the producing party shall mark the copies of such documents as may contain protected

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subject matter with the appropriate designation at the time the copies are produced to the inspecting party.

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- 4. If any Confidential Information is produced by a third party to this litigation, such third party shall be considered a "designating party" within the meaning of that term as it is used in the context of this Order and both parties to this Order should be treated as receiving parties.
- 5. Confidential Information that originated with a third party, subject to the terms of any confidentiality obligation to that third party, may be designated as "Confidential" and shall, once designated, be subject to the restrictions on disclosure specified in Paragraph 7.
- 6. In the event any designating party produces Confidential Information that has not been designated "Confidential" or not correctly designated, the designating party may designate or redesignate the information to the same extent as it may have designated the information before production by a subsequent notice in writing specifically identifying the redesignated information accompanied by a replacement set of such misdesignated documents bearing a "Confidential" designation thereon, in which event the parties shall henceforth treat such information in accord with this Protective Order, and shall undertake their best efforts to correct any disclosure of such information contrary to the redesignation. Further, the receiving party shall immediately return the documents that lacked the "Confidential" designation to the designating party upon receiving the replacement set of documents bearing the "Confidential" designation. No showing of error, inadvertence, or excusable neglect shall be required for such redesignation.

#### **Disclosure of Confidential Information**

7. Information designated "Confidential" shall not be given, shown, made available or communicated in any way to any person or entity other than the following:

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a. Litigation counsel for The Rockefeller University and Chiron

Corporation:

- i. Kaye Scholer LLP
- ii. McKool Smith P.C.
- b. Litigation counsel for Centocor, Inc.:
  - i. Sidley Austin Brown & Wood LLP
  - ii. Young, Pickett & Lee
- c. Litigation counsel for Abbott Laboratories:
  - i. Winston & Strawn LLP
  - ii. The Roth Law Firm
- d. Members or employees of any of the foregoing law firms assisting in this litigation as well as any independent litigation support providers retained by such firms to assist in this litigation (*e.g.*, outside copy services, graphic artists and visual aid providers, and jury consultants).
- e. The Court and Court personnel and stenographic/videographic reporters at depositions taken in this action.
- f. The in-house counsel listed below, as well as the non-lawyer employees within the legal department who assist them, provided, however, that no person who is currently involved in the preparation or prosecution of any U.S. or foreign patent application that claims priority based on any of the applications that led to the patents-in-suit will be permitted access to any Confidential Information, whether listed below or not:

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- i. For plaintiff The Rockefeller University: Harriet S. Rabb,
   Teresa L. Solomon, and Deborah Y. Yeoh.
- ii. For plaintiff Chiron Corporation: Lisa Alexander, Ursula Bartels, Robert Blackburn, Steven Collier, Alisa Harbin, Jessica Hoover, Nancy Koch, and Ethan Knowlden.
- iii. For defendant Centocor, Inc. and/or its corporate parent Johnson & Johnson: Eric Harris, Steven Berman, Kenneth Dow, Taysen van Itallie, and Philip Johnson.
- iv. For defendant Abbott Laboratories: Laura Schumacher,
  Jose Rivera, Sarah Lyke, Lawrence Pope, Mimi Goller, and Rob DeBerardine.
- g. Independent consultants or experts and their staff not employed by or affiliated with a party or with a party's licensee or licensor, retained by the attorneys for the parties either as technical consultants or expert witnesses for the purposes of this litigation, provided that (i) such persons have complied with the procedure of Paragraph 12 herein, and (ii) agree in writing to be bound by the provisions of this Order, in the form set forth as Exhibit A, hereto.
- h. The list of persons to whom Confidential Information may be disclosed may be expanded or modified by mutual agreement in writing by counsel for the designating party and the receiving party without necessity of modifying this Order.
- i. The receiving party shall give notice of this Order and advise of the duty to comply with its terms to any person allowed access to Confidential Information prior to allowing said person access to Confidential Information.

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#### No Waiver of Privileges

8. Inadvertent production of documents or information subject to attorneyclient privilege, work product immunity, or any other applicable privilege or immunity shall not
constitute a waiver of, nor a prejudice to, any claim that such or related material is privileged or
protected by the work product immunity, provided that the designating party notifies the
receiving party in writing promptly after discovery of such inadvertent production. Such
inadvertently produced documents and all copies thereof shall promptly be returned to the
designating party upon request. No use shall be made of such documents other than to challenge
the propriety of the asserted privilege or immunity, nor shall they be shown to anyone who has
not already been given access to them subsequent to the request to return them. No
demonstration or proof of error, inadvertence, excusable neglect, or absence of negligence shall
be required of the designating party in order for such party to avail itself of the provisions of this
paragraph.

### **Use and Control of the Confidential Information**

- 9. All Confidential Information disclosed pursuant to this Order shall be used by any recipient thereof solely for the purposes of this litigation, and not for any business or competitive or other purposes. It shall be the duty of each party and each individual having notice of this Protective Order to comply with this Order from the time of such notice.
- 10. All depositions shall be marked "CONFIDENTIAL" regardless of whether a designation of confidentiality was made on the record or otherwise and shall be subject to this Protective Order, unless and until the receiving party makes a request to the party producing the witness or counsel for the witness to release the deposition or any portion thereof from Confidential treatment, and only if, and to the extent, the party producing the witness or counsel for the witness agrees in writing to the modification of treatment of all or part of the transcript, or

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unless the Court so orders. If the party producing the witness or counsel for the witness fails to respond to such a request within 14 days, the receiving party may move the Court for an order releasing the requested transcript or portion thereof from Confidential treatment.

- 11. All Confidential Information that is filed with the Court, and any pleadings, motions or other papers filed with the Court disclosing any Confidential Information, shall be filed and maintained in Court under seal. Where practical, only confidential portions of filings with the Court shall be filed under seal.
- Paragraph 7(g), the party seeking to provide such access must give written notice to the attorneys for the designating party of the intention to make such disclosure, stating the name, address, and a resume of the background and qualifications of the person to whom disclosure is proposed. Within ten (10) days from the service of such written notice, the designating party may object to such disclosure by service of a written notice of objection on the attorneys for the party seeking to make the disclosure, stating the reasons for the objection. No disclosure of Confidential Information to any such person may occur prior to the expiration of ten (10) days from the date of service of the written notice of intent to disclose unless consent is granted earlier by the designating party. If the designating party gives notice of objection to disclosure, the party seeking to make the disclosure must seek leave of the Court to make the disclosure and may not make such disclosure without an order of the Court authorizing such disclosure.
- 13. Nothing in this Order shall prevent or otherwise restrict counsel for a party from rendering legal advice to such party with respect to the litigation and, in the course thereof, relying upon an examination of Confidential Information; provided, however, that in rendering

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such advice and in otherwise communicating with the party, counsel shall not disclose Confidential Information.

- Confidential Information in any manner that it considers appropriate. Additionally, counsel for either party shall be entitled to show or use Confidential Information obtained from another party, during examination, either at deposition or at any hearing or trial, of any officer, employee or retained expert of the designating party. Counsel for either party shall also be entitled to show or use Confidential Information obtained from another party, during examination, either at deposition or at any hearing or trial, of any person who is apparently an author, creator or recipient of the Confidential Information.
- 15. If a party intends to reveal Confidential Information of another party during a trial, court appearance or hearing which is open to the public, the party intending to reveal such Confidential Information shall provide notice and opportunity to object, unless consent from the designating party is previously obtained.

#### **Duration of Order, Objections, Modifications**

- 16. This Protective Order shall remain in force and effect until modified, superseded or terminated by order of this Court, which may be entered pursuant to agreement of the parties hereto. This Protective Order shall continue in effect after termination of this action and continue to be binding upon all persons to whom Confidential Information is disclosed hereunder.
- 17. Upon final termination of this action (including all appeals) the receiving party shall, within thirty (30) days of such termination, either return to the designating party or destroy all Confidential Information in its possession. In either event, the receiving party shall describe the materials returned or destroyed and certify their return or destruction, with the

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exception that outside counsel and the persons designated in Paragraph 7(f) may retain (i) copies of the pleadings or other papers filed with the Court or served in the course of the litigation, depositions transcripts, deposition exhibits and the trial record; and (ii) one file copy of all documents produced in the course of discovery. Nothing herein shall restrict the ability of the parties or their counsel to retain information or documents not designated as Confidential Information by the producing party.

- 18. If the receiving party learns that Confidential Information produced to it is disclosed to or comes into the possession of any person other than in the manner authorized by this Order, the receiving party responsible for the disclosure must immediately inform the designating party of such disclosure and shall make a good faith effort to retrieve any documents or things so disclosed and to prevent disclosure by each unauthorized person who received such information.
- 19. Any receiving party may at any time request that the designating party remove the "Confidential" designation with respect to any document, object or information. Such request shall be served on counsel for the designating party, and shall particularly identify the designated Confidential Information that the receiving party contends is not confidential and the reasons supporting its contention. If the designating party does not agree to remove the "Confidential" designation within 14 days, then the party contending that such documents or information are not Confidential may file a motion to remove such information from the restrictions of this Order.

#### Miscellaneous

20. This Protective Order may be modified only by written agreement of the parties or further order of the Court and is without prejudice to the rights of any party or third party to seek additional or different relief from the Court not specified in this Order.

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- 21. The designation by counsel for the designating party of any document, material or information as constituting or containing Confidential Information is intended solely to facilitate the preparation and trial of this case, and such designation shall not be construed in any way as an admission or agreement by any party that such document, material or information constitutes or contains any Confidential Information as a matter of law.
- 22. Any court reporter who transcribes testimony in this action at a deposition shall agree, before transcribing any such testimony, that all Confidential testimony is and shall remain confidential and shall not be disclosed except as provided under this Order and that copies of any transcript, reporter's notes or any other transcription records of any such testimony shall be retained in absolute confidentiality and safekeeping by such shorthand reporter or shall be delivered to an attorney of record or filed with the Court.
- 23. In the event Confidential Information disclosed during the course of the litigation is sought by any person or entity not a party to this litigation, whether by subpoena in another action or service with any legal process, the party receiving such subpoena or service shall promptly notify in writing outside counsel for the designating party if such subpoena or service demands the production of Confidential Information of such designating party. Any such person or entity seeking such Confidential Information by attempting to enforce such subpoena or other legal process shall be apprised of this Protective Order by outside counsel for the party upon whom the subpoena or process was served. Nothing herein shall be construed as requiring anyone covered by this Protective Order to contest a subpoena or other process, to appeal any order requiring production of Confidential Information covered by this Protective Order, or to subject itself to penalties for non-compliance with any legal process or order.

- 24. In the event anyone shall violate or threaten to violate the terms of this Stipulated Protective Order, the aggrieved party immediately may apply to obtain injunctive relief against any such person violating or threatening to violate any of the terms of this Stipulated Protective Order, and in the event that the aggrieved party does so, the responding party, subject to the provisions of this Stipulated Protective Order, shall not employ as a defense thereto the claim that the aggrieved party possesses an adequate remedy at law.
- 25. Nothing herein shall prevent any party or non-party from seeking additional or different relief from the Court not specified in this Order.
- 26. The section titles in this Order are for convenience of organization only, and are not part of, nor are they relevant to the construction of this Order.

SIGNED this 11th day of March, 2005.

T. JOHN WARD

UNITED STATES DISTRICT JUDGE

John Wars

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**AGREED TO:** 

Attorneys for The Rockefeller University and Chiron Corporation:

DATE: March 10, 2005

By /s/ Sam Baxter

Sam Baxter

Texas State Bar No. 01938000

McKool Smith P.C. 505 E. Travis, Suite 105

P.O. Box 0

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By /s/ Sylvia Becker (w/permission SB)

Sylvia Becker

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901 15th St. N.W., Suite 1100

Washington, DC 20005

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sbecker@kayescholer.com

Attorneys for Centocor, Inc.:

By /s/ Damon Young (w/permission SB)

Damon Young

Texas State Bar No. 22176700

YOUNG, PICKETT & LEE

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By /s/ David T. Pritikin (w/permission SB)

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Attorneys for Abbott Laboratories:

By /s/ Carl R. Roth (w/permission SB)

Carl R. Roth Texas State Bar No. 17312000 THE ROTH LAW FIRM P.O. Box Drawer 876 115 N. Wellington, Suite 200 Marshall, Texas 75670

Telephone: (903) 935-1665 Telecopier: (903) 935-1797

cr@rothfirm.com

By \_\_\_\_\_/s/ George C. Lombardi (w/permission SB)

George C. Lombardi WINSTON & STRAWN LLP 35 West Wacker Dr. Chicago, Illinois 60601

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#### **EXHIBIT A**

### IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF TEXAS MARSHALL DIVISION

1. THE ROCKEFELLER UNIVER	SITY§	
and	§	
2. CHIRON CORPORATION,	§	
	§	
Plaintiffs,	§	
	§	CIVIL ACTION NO. 2-04CV-168-TJW
v.	§	
	§	
1. CENTOCOR, INC.	§	
and	§	
2. ABBOTT LABORATORIES	§	
	§	
Defendants.	§	

### **DECLARATION OF COMPLIANCE**

I,	do declare and state as follows:
1.	I live at I am employed as (state position)
 	by (state name and address of employer)
 	·
2.	I have read the Protective Order entered in this case, a copy of which has

- 2. I have read the Protective Order entered in this case, a copy of which has been given to me.
- 3. I understand and agree to comply with and be bound by the provisions of the Protective Order and consent to the jurisdiction of the district court to enforce the terms of the Protective Order, including that upon receipt of any Confidential Information, I will be personally subject to it, and to all of its requirements and procedures.

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			_		(Signature	<del>)</del>	<u></u>
Executed this	Continue of the Continue of th	day of					
perjury under	the law	s of the Unit	ed States of	America, tha	at the foregoin	ng is true and co	rrect
	4.	Further, I d	eclare, as pro	ovided by 28	3 U.S.C. § 174	6, under penalt	y of

# EXHIBIT - C

MORRISON & FOERSTER LLP Rachel Krevans, admitted pro hac vice 415 Market Street San Francisco, CA 94105-2482 Telephone: (212) 468-8000 Facsimile: (212) 468-7900

William J. Kuhne 1290 Avenue of the Americas New York, New York 10104-0012 Telephone: (212) 468-8000

Facsimile: (212) 468-7900

Attorneys for Defendant Novartis Vaccines and Diagnostics, Inc.

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

DR. ANTHONY CERAMI,

1:07-CV-05634-AKH-DFE

Plaintiff, -against-

**NOVARTIS VACCINES AND DIAGNOSTICS, INC.'S INITIAL DISCLOSURES** 

NOVARTIS AG and NOVARTIS VACCINES AND DIAGNOSTICS, INC.,

**ECF CASE** 

Defendants.

Pursuant to Rule 26(a)(1) of the Federal Rules of Civil Procedure, Defendant Novartis Vaccines and Diagnostics, Inc. ("Defendant") hereby provides the following initial disclosures. These initial disclosures are based solely on the information available to Defendant at the present time based on a reasonable search, and are made without prejudice to Defendant's right to present additional evidence, including, but not limited to, evidence obtained through discovery or through continued investigation in this action or any future filing or proceeding, including, but not limited to, at trial. Defendant accordingly reserves the right to supplement or amend these initial disclosures in the future.

Information or materials protected by the attorney-client privilege and/or the work product doctrine will not be disclosed as a part of these initial disclosures. Defendant reserves the right to object in this action or any other action to the production and/or introduction into evidence of these disclosures, any document within the categories described below and/or testimony by any of the disclosed witnesses on any proper ground, and reserves the right to object on any proper ground to any discovery request or proceeding involving or relating to the subject matter of these disclosures.

#### I. **IDENTIFICATION OF INDIVIDUALS**

Pursuant to Rule 26(a)(1)(A) of the Federal Rules of Civil Procedure, Defendant identifies the following individuals as currently expected to have discoverable information that Defendant may use to support its claims or defenses, unless solely for impeachment. Defendant expects to obtain the identity of other individuals who have discoverable information through discovery. Defendant does not concede that the individuals listed herein necessarily have discoverable information. Further, the present and former employees of Defendant identified below should be contacted solely through Morrison & Foerster LLP.

Individual	Issue(s)
Dr. Juerg Baenziger	The litigation against Abbott and Centocor (the
4560 Horton Street	"TNF litigation") and Dr. Cerami's claim for unjust
Emeryville, CA 94608	enrichment.
510-923-2993	
Dr. Anthony Cerami	The consulting agreement between Dr. Cerami and
	Chiron; payments received by Dr. Cerami during the
	time period put at issue in the complaint; the TNF
	litigation; the inventions set forth in the patents at
	issue in the TNF litigation and the work that led to
	those inventions; all matters referenced in Dr.
	Cerami's complaint.
Masanobu Kawakami	The inventions set forth in the patents at issue in the
	TNF litigation and the work that led to those
	inventions.
Nancy Koch, Esq.	The TNF litigation and Dr. Cerami's claim for

	unjust enrichment.
Dr. Edward Penhoet President Gordon and Betty Moore Foundation Presidio of San Francisco P.O. Box 29910 San Francisco, CA 94129-0910 415-561-7700	The consulting agreement between Dr. Cerami and Chiron, the license agreement between The Rockefeller University ("Rockefeller") and Chiron, and related matters.
Dr. William J. Rutter 863 Mitten Road, Suite 101 Burlingame, CA 94010 415-344-0844	The consulting agreement between Dr. Cerami and Chiron, the license agreement between Rockefeller and Chiron, and related matters.
One or more individuals from Rockefeller University	Dr. Cerami's employment with Rockefeller; the license agreement between Rockefeller and Chiron; compensation paid to Dr. Cerami.
Individuals identified in Plaintiff's initial disclosures	Issues identified in Plaintiff's initial disclosures.

#### II. **DOCUMENTS AND THINGS**

Pursuant to Rule 26(a)(1)(B) of the Federal Rules of Civil Procedure, Defendant hereby describes by category and location the documents, data compilations, and tangible things that are in its possession, custody, or control and that it may use to support its claims or defenses, unless solely for impeachment:

- 1. The license agreement with Rockefeller, as amended, and correspondence related thereto.
- 2. The August 16, 1985, consulting agreement with Cerami and correspondence related thereto.
- 3. United States Patents 6,309,640 and 6,419,927 and related documents.
- 4. Documents reflecting payments made to Dr. Cerami.
- 5. The settlement agreements with Centocor and Abbott and related documentation, which are subject to confidentiality agreements.
- 6. The July 9, 2001, litigation consulting agreement.

- 7. Certain documents from the TNF litigation that are currently subject to the protective order entered therein.
- 8. The documents, electronically stored information, and/or tangible things identified by Defendant in its initial disclosures.

The foregoing documents are located generally at Defendant's offices in Emeryville, California, the offices of Defendant's counsel, Morrison & Foerster LLP, in New York, New York, the offices of Defendant's counsel in the TNF litigation, Kaye Scholer, and/or in the Plaintiff's possession, custody, or control. Defendant notes that its investigation is ongoing and that additional documents may be within its possession, custody or control and will be identified if and when located.

#### III. **COMPUTATION OF DAMAGES**

Pursuant to Rule 26(a)(1)(C) of the Federal Rules of Civil Procedure, Defendant states that it is not claiming damages in this litigation.

#### IV. **INSURANCE AGREEMENTS**

Pursuant to Rule 26(a)(1)(D) of the Federal Rules of Civil Procedure, Defendant states that it has no such documents.

Defendant expressly reserves the right to supplement the disclosures set forth herein, including the identification of individuals, and identification of additional documents and materials if such information comes to its attention through further investigation, discovery or otherwise.

Dated: October 11, 2007

New York, New York

MORRISON & FOERSTER LLP

Attorneys for Plaintiff 1290 Avenue of the Americas New York, New York 10104 (212) 468-8000

Rachel Krevans, admitted pro hac vice 425 Market Street San Francisco, CA 94105-2482 415.268.7000

#### **CERTIFICATE OF SERVICE**

I, Rachel L. Quitkin, hereby certify that on this day, October 11, 2007, I caused a true and correct copy of the Novartis Vaccines and Diagnostics, Inc.'s INITIAL DISCLOSURES to be served via overnight mail upon the following:

Barry J. Brett, Esq. Troutman Sanders LLP The Chrysler Building 405 Lexington Avenue New York, NY 10174

Attorneys for Plaintiff, Anthony Cerami

Dated:

New York, New York

October 11, 2007

Rachel L. Quitkin, Esq.

# EXHIBIT - D

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## Warren Pharmaceuticals, Inc.

Corporate Biograp

is a privately held biotech company incorporated in 2001 for the purpose of developing proprietary tissue-protective technologies.

HOME

OUR COMPANY

SCIENCE AND TECHNOLOGY

DISEASE AREAS

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CONT INFORM

Anthony Cerami, PhD
Founder
Chief Executive Officer
Chairman of the Board of Directors
Member, Scientific Advisory Board

Anthony Cerami, PhD is the founder of Warren Pharmaceuticals, Inc. and serves as its Chairn Board and CEO.

A member of the National Academy of Sciences and former dean of The Rockefeller Universit Cerami has had a successful career applying detailed biochemical insights to the design of no therapeutic strategies, translating scientific discovery into commercially viable products of high utility.

He received his PhD from The Rockefeller University in 1967 and completed postdoctoral fello Harvard Medical School and at the Jackson Laboratory in Bar Harbor, Maine. Dr. Cerami servas Professor and Head of the Laboratory of Medical Biochemistry and as Dean of Graduate ar Graduate Studies of Rockefeller University.

He established the Picower Institute for Medical Research in Manhasset, New York, in July 19 became its first president. He is a recipient of a number of awards, including the Luft Award in and the Banting Medal for Scientific Achievement, awarded by the American Diabetes Associarecognition of his lifelong work on diabetes.

Dr. Cerami has been the inventor or co-inventor on over 150 issued U.S. patents and hundred counterparts. He is the author or co-author of over 500 scientific publications, and is the co-invanti-TNF monoclonal antibody that has been approved by the FDA for the treatment of Crohn's and rheumatoid arthritis.

Dr. Cerami is also the inventor of the hemoglobin A1c test that is used by diabetics worldwide.

# EXHIBIT - E

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### Warren Pharmaceuticals, Inc.

with its strategic partners is pursuing an offensive and defensive intellectual property strategy to secure freedom to operate in the tissue protective cytokine arena while preventing others from approaching its proprietary platform.

- IP Overview
- · Issued and Published Pate
- Current Ailiances

HOME

OUR COMPANY

SCIENCE AND TECHNOLOGY

DISEASE AREAS

INTELLECTUAL ASSETS

LUN

## Overview

Warren Pharmaceuticals has an established patent strategy aimed at securing exclusivity in the arena of tissue protective cytokine technology. Numerous US and international applications have been filed seeking to protect Warren's novel tissue protective cytokines, and uses of tissue protective cytokines to protect, repair or enhance tissue function.

To date, the U.S. Patent Office has since granted one of these patents, U.S. Patent No. 6,531,121, for the use of tissue protective cytokines based on asialoerythropoietin to protect, repair and enhance tissue function.

### Issued and **Published**

## **Patents**

**US Patent or US/PCT Publication** Issue / Publication date Title

#### Summary

#### U.S. Patent 6,531,121B2 March 11, 2003

Protection and

enhancement of erythropoietin-responsive cells, tissues and organs

Methods and compositions are provided for protecting or enhancing erythropoietin-responsive cell, tissue, organ and bodily part function and viability in vivo, in situ or ex vivo in mammals including human beings by systemic or local administration of an erythropoietin receptor activity modulator, such as an erythropoietin

#### WO0061164

October 19, 2000

Modulation of excitable tissue function by peripherally administered erythropoietin

Methods and compositions are provided for protecting or enhancing excitable tissue function in mammals by systemic administration of an erythropoietin receptor activity modulator, such as erythropoietin, which signals vi an EPO-activated receptor to modulate the function of excitable tissue. Excitable tissues include central neuronal tissues, such as the brain, peripheral neuronal tissues, retina, and heart tissue. Protection of excitable tissues provides treatment of hypoxia, seizure disorders. neurodegenerative diseases, hypoglycemia, and neurotox poisoning. Enhancement of function is useful in learning and memory. The invention is also directed to composition and methods for facilitating the transport of molecules across endothelial cell tight junction barriers, such as the blood-brain barrier, by association of molecules with an erythropoietin receptor activity modulator, such as an erythropoietin.

#### WO0253580A2

July 11, 2002

Methods and compositions are provided for protecting or

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Protection, restoration, and enhancement of erythropoietin-responsive cells, tissues and organs enhancing an erythropoietin-responsive cell, tissue, organ or body part function or viability in vivo, in situ or ex vivo in mammals, including human beings, by systemic or local administration of an erythropoietin receptor activity modulator, such as an erythropoietin or a modified erythropoietin.

## US2003/0072737A1

April 17, 2003

Tissue protective cytokines for the protection, restoration, and enhancement of responsive cells, tissues and organs

Methods and compositions are provided for protecting or enhancing a responsive cell, tissue, organ or body part function or viability in vivo, in situ or ex vivo in mammals, including human beings, by systemic or local administratio of a tissue protective cytokine

#### US2003/0104988A1

June 5, 2003

Protection, restoration, and enhancement of erythropoietin-responsive cells, tissues and organs Methods and compositions are provided for protecting or enhancing an erythropoietin-responsive cell, tissue, organ or body part function or viability in vivo, in situ or ex vivo in mammals, including human beings, by systemic or local administration of an erythropoietin receptor activity modulator, such as an erythropoietin or a modified erythropoietin

#### US2003/0134798A1

July 17, 2003

Protection and enhancement of erythropoietin-responsive cells, tissues and organs Methods and compositions are provided for protecting or enhancing erythropoietin-responsive cell, tissue, organ anbodily part function and viability in vivo, in situ or ex vivo in mammals including human beings by systemic or local administration of an erythropoietin receptor activity modulator, such as an erythropoietin

#### WO0403176

January 8, 2004

Recombinant tissue protective cytokines and encoding nucleic acids thereof for protection, restoration, and enhancement of responsive cells, tissues, and organs

Methods and compositions are provided for protecting or enhancing a responsive cell, tissue, organ or body part function or viability in vivo, in situ or ex vivo in mammals, including human beings, by systemic or local administratio of an erythropoietin receptor activity modulator, such as ar recombinant tissue protective cytokine.

### WO0404656

January 15, 2004

Tissue protective cytokines for the protection, restoration, and enhancement of responsive cells, tissues and organs

Methods and compositions are provided for treating a mammal having inflammation by protecting or enhancing a responsive cell, tissue, organ or body part exhibiting or associated with the inflammation, by systemic or local administration of a composition comprising a tissue protective cytokine. The invention also encompasses combination treatments comprising administering a composition comprising a tissue protective cytokine of the

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	invention and administering at least one anti-inflammatory or least one immunomodulatory agent.
WO0422577 March 18, 2004  Long acting erythropoietins that maintain tissue protective activity of endogenous erythropoietin	Methods for increasing the hematocrit of an individual whill maintaining the tissue protective activities of endogenous through the administration of a pharmaceutical compound containing chemically modified long acting erythropoietin. Also disclosed are the new chemically modified long acting erythropoietins, methods of producing the chemically modified long acting erythropoietins, and compositions comprising the chemically modified long acting erythropoietins.
WO2004/096148 November 11, 2004  Methods for identifying compounds that have a tissue protective activity using a heteromultimer receptor complex that mediates the tissue protective activities.	The complex consists of at least one EPO-R in complex with at least one ßc Receptor. These compounds used in the assays to identify tissue protective compounds include but are not limited to, small molecules and biologics. The compounds identified using these assays can be used to treat or prevent various diseases, disorders, or conditions of the central and peripheral nervous systems as well as those of other erythropoietin-responsive or excitable cells, tissues, and organs.
WO2004/112693 December 29, 2004 Tissue protective cytokines with an extended therapeutic window	Methods and uses for a pharmaceutical composition with an erythropoietin or a tissue protective cytokine for protecting or restoring function to a responsive cell, tissue, organ or body part function or viability in mammals when administered outside of the therapeutic window of previously approved therapeutics.
WO2005/025606 March 24, 2005  Long acting erythropoietins that maintain tissue protective activity of endogenous erythropoietin	Methods for increasing the hematocrit of an individual whill maintaining the tissue protective activities of endogenous erythropoietin through the administration of a pharmaceutical compound containing chemically modified long acting erythropoietin. Also disclosed are the new chemically modified long acting erythropoietins, methods of producing the chemically modified long acting erythropoietins, and compositions comprising the chemically modified long acting erythropoietins.
WO2005/032467 April 14, 2005 Tissue protective cytokines for the treatment and prevention of sepsis and the formation of adhesions	A method of treating, preventing, delaying the onset, and/c reducing the effects of proinflammatory cytokines in conditions including, but not limited to, sepsis, adhesion formation, wounds, organ failure, chronic disease, general inflammatory conditions resulting from infection, scarring resulting from injury and incisions, and combinations thereof.
WO 2005/084364 September 15, 2005 Long acting tissue	Methods and compositions are provided for protecting or enhancing a responsive cell, tissue, organ or body part function or viability in vivo, in situ or ex vivo in mammals, including human beings, by systemic or local administratio

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protective cytokines for the protection, restoration, and enhancement of responsive cells, tissues and organs	of a long acting tissue protective cytokine. In particular, the long acting tissue protective cytokines of the present invention relate to modified long acting erythropoietins exhibiting a tissue protective effect without an erythropoiet related activity.
WO 2005/117927 December 15, 2005 Tissue protective cytokines with an extended therapeutic window	Methods and uses are provided for a pharmaceutical composition with an erythropoietin or a tissue protective cytokine for protecting or restoring function to a responsive cell, tissue, organ or body part function or viability in mammals when administered outside of the therapeutic window of previously approved therapeutics.
WO 2006/014466 February 9, 2006  Novel carbamylated epo and method for its production	The present invention comprises an optimal process for carbamylation yielding a product with a low degree of polymerisation and aggregation. The fully carbamylated erythropoietin with all of the N-terminal and all lysine residues was obtained. The resulting fully carbamylated pure EPO is along with pharmaceutical compositions comprising the compound are part of the invention.

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